Application No.:

10/509,498

Filing Date:

October 27, 2004

AMENDMENTS TO THE CLAIMS

1. (**Currently amended**) An immunogenic composition suitable for administration to a vertebrate host which comprises:

(a) a polynucleotide immunogenic component consisting of at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide immunogenic component into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic Th1 immune response;

(ba) a composition comprising a protein antigen immunogenic component eonsisting of comprising at least one protein antigen selected from the group consisting of model protein antigens and immunogenic protein antigens so as to induce a prophylaetic or therapeutic Th2 immune response and a mineral-based, negatively charged adjuvant; and

(eb) a polynucleotide immunogenic component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide immunogenic component into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response one adjuvant, which is a mineral-based, negatively charged adjuvant,

said composition produced by a method comprising preincubating or subsequently mixing said mineral-based negatively charged adjuvant with said at least one protein antigen immunogenic component to form the composition of (a) prior to formulating with said polynucleotide immunogenic component.

- 2. (**Previously presented**) The immunogenic composition according to claim 1 wherein said mineral-based negatively charged adjuvant is an aluminum salt or a calcium salt.
- 3. (**Previously presented**) The immunogenic composition according to claim 2 wherein said aluminum or calcium salt is selected from the group consisting of aluminum phosphate, aluminum hydroxyphosphate, phosphate-treated aluminum hydroxide, calcium phosphate, calcium hydroxyphosphate, and phosphate-treated calcium hydroxide.

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4. (**Previously presented**) The immunogenic composition according to claim 1 wherein said group of model protein antigens range from acidic isoelectric point (IEP) proteins to alkaline IEP proteins.

- 5. (**Previously presented**) The immunogenic composition according to claim 1 wherein said group of immunogenic protein antigens is selected from the group consisting of a surface protein or a core protein of Hepatitis B virus (HBV), a de-toxified toxin from the bacteria *Clostridium tetani* (a tetanus toxoid), a de-toxified toxin from the bacteria *Clostridium botulinus* (a botulinus toxoid), and a de-toxified toxin from the bacteria *Corynebacterium diphtheriae* (a diphtheria toxoid).
- 6. (**Previously presented**) The immunogenic composition according to claim 1 wherein said group of immunogenic protein antigens comprises protein antigens derived from inactivated poliovirus.
 - 7. (Canceled)
- 8. (**Previously presented**) A kit comprising an immunogenic composition as defined in claim 1 in a unit dose form for administration to a vertebrate recipient.
- 9. (**Previously presented**) A method of making the combined immunogenic composition as defined in claim 1, comprising preincubating or subsequently mixing the mineral-based, negatively charged adjuvant with said at least one protein antigen immunogenic component; and adding said polynucleotide immunogenic component to the adjuvant protein mixture to form the combined immunogenic composition, wherein the immunogenic composition is capable of inducing a prophylactic or therapeutic Th1 and Th2 immune response.
- 10. (**Currently amended**) An immunogenic composition suitable for administration to a human host which comprises:
 - _(a) a polynucleotide immunogenic component consisting of at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide immunogenic component into said human host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic Th1 immune response;
 - (ba) a composition comprising a protein antigen immunogenic component consisting of comprising at least one protein antigen selected from the group consisting of

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model protein antigens and immunogenic protein antigens <u>and a mineral-based</u>, <u>negatively charged adjuvantso as to induce a prophylactic or therapeutic Th2 immune response</u>; and

(eb) a polynucleotide immunogenic component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide immunogenic component into said human host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response a mineral-based, negatively charged adjuvant, wherein said mineral-based negatively charged adjuvant is preincubated or subsequently

mixed with said at least one protein antigen immunogenic component to form the composition of (a) prior to formulating with said polynucleotide immunogenic component.

- 11. (**Previously presented**) A kit comprising an immunogenic composition as defined in claim 1 in a unit dose form for administration to a human recipient.
- 12. (**Previously presented**) A method for preparing the immunogenic composition according to claim 1, wherein a mineral-based negatively charged adjuvant is preincubated or subsequently mixed with at least one protein antigen immunogenic component prior to formulating with a polynucleotide immunogenic component, wherein the immunogenic composition is capable of inducing a prophylactic or therapeutic Th1 and Th2 immune response.